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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,862	08/31/2001	Kevin P. Baker	P2548P1C12	4824

7590

07/29/2003

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EXAMINER

VOGEL, NANCY S

ART UNIT

PAPER NUMBER

1636

14

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/944,862

Applicant(s)

BAKER ET AL.

Examiner

Nancy T. Vogel

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27-32 and 35-37 is/are allowed.
- 6) ☒ Claim(s) 22-26, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This action is in response to the amendment filed 5/15/03, Paper No. 13.

Claims 22-37 are pending in the case. Claims 22-26, 33 and 34 remain rejected.

Claims 27-32, and 35-37 are allowed.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

The priority date for claims 22-37 remains 1 December 1999 for reasons made of record in the previous Office action mailed 2/11/03, and for the reasons set forth below.

The rejection of claims 22-27, 30, 31, 33 and 34 under 35 U.S.C. 112, first paragraph, has been withdrawn in view of applicant's amendment to the claims.

Claims 22-26, 33 and 34 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for reasons of record and for the reasons set forth below.

Response to Amendment

With regard to the priority issue, applicants have argued that the claims should be given priority for the pending claims to application 09/254,311, since the '311 application discloses the polypeptide and asserts "several specific, substantial and credible utilities for the claimed invention" and "the '311 application discusses the use of the claimed invention in protein-protein binding assays, biochemical screening assay, immunoassays and cell based assays" (page 7 of the response). However, as was stated in the previous Office action, the parent application 09/254,311 did not contain an enabling disclosure. The specification of 09/254,311 teaches that PRO361 is possibly a mucin or a chitinase, however any use based on these speculations is not enabled. Since PRO361's activity of inhibiting proliferation of stimulated T-lymphocytes is not disclosed in the parent or provisional application and cannot be predicted from the teachings of the parent application or provisional application, the parent or provisional application is not enabling for the instantly claimed invention. Thus, the requirements of the first paragraph of 35 USC 112 have not been met. Whether a specific, substantial and credible utility was stated in the parent application is not at issue here. Therefore, it is maintained that the priority date for the instant claims is 1 December 1999.

With regard to the rejection of claims 22-26, 33 and 34 under 35 USC 112, first paragraph for failing to comply with the written description requirement, Applicant's

arguments filed 5/15/03 in Paper No. 13 have been fully considered but they are not persuasive.

Applicants have argued that the inclusion in claims 22-26 of a functional limitation distinguishes the polypeptides belonging to the claimed genus from those excluded from the genus, and that the structural and functional characteristics are fully described in the specification as filed. However, the inclusion in the claims of a function for the claimed polypeptides does not remedy the lack of written description in the specification of a representative number of species encompassed by the claims so that one of skill in the art could envision all the polypeptides that may inhibit proliferation of stimulated T-lymphocytes. There is no discussion in the specification of common structural feature(s) of the genus encompassed by the claims that play a role in the inhibition of proliferation of T-cell lymphocytes. There is no disclosure of the amino acids in the hydrophobic core of the protein essential to proper folding. Therefore, the specification does not describe the claimed isolated polypeptides in such full, clear, concise and exact terms so as to indicate that Applicant had possession of these isolated polypeptides at the time of filing the present application. Thus, the written description requirement has not been satisfied, and the rejection is maintained.

Applicant is requested in the future to refer to sections in the specification by page and line number, rather than paragraph number (i.e. "Support for new claims 35 and 36 may be found throughout the specification, including paragraph 596" (page 6 of Paper No. 13)).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (703) 308-4548. The examiner can normally be reached on 7:30 - 4:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

July 24, 2003


TERRY MCKELVEY
PRIMARY EXAMINER